

Application No. 09/916611
Reply to Office Action of December 6, 2005

Docket No.: 00306-00142-USU

Appendix 1

United States Environmental Protection Agency Prevention, Pesticides and Toxic Substances
EPA 712-C-96-020 (7101) August 1996

Product Properties Test Guidelines

OPPTS 830.6303

Physical State

Introduction

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, et seq.).

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OPPTS 830.6303 Physical state.

(a) Scope--(1) Applicability. This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, et seq.).

(2) Background. The source material used in developing this harmonized OPPTS test guideline is OPP guideline 63-3 Physical state (Pesticide Assessment Guidelines, Subdivision D: Product Chemistry, EPA Report 540/9-82-018, October 1982) and 40 CFR 158.190 Physical and chemical characteristics.

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(b) Test method--(1) Objective. Data on the physical and chemical characteristics of pesticide active ingredients and products are used to confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process used to produce the pesticide or product. Physical state, color, and odor are needed for the Agency to respond to emergency requests for identification of unlabeled pesticides involved in accidents or spills. Physicians, hospitals, and poison control centers also request this information to aid in their identification of materials implicated in poisoning episodes.

(2) Test details. The description of the physical state of each substance shall be based on a visual inspection of the substance at 20 deg.C or 25 deg.C.

(c) Reporting. (1) Report the physical state including the form of the substance. Conventional terms such as "solid," "granular," "semi-solid," "crystalline solid," "amorphous solid," "mixture of liquid and solid," "aqueous solution," "emulsion," "volatile liquid," "powder," "gas," and similar terms such as those used to describe compounds in the "Handbook of Chemistry and Physics" (see paragraph (d) of this guideline) shall be used, as appropriate, to describe each substance.

(2) Any methods used to characterize the physical properties of a pesticide shall be referenced or described in the application for registration. If the methods used are listed in paragraph (d) of this guideline, reference to the method will suffice. If other methods are used, copies of such methods must be submitted with the application.

(d) References. The following references should be consulted for additional background material on this test guideline.

(1) Handbook of Chemistry and Physics, CRC Publishing Co., Boca Raton, FL, latest edition.

(2) [Reserved]